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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,680	10/17/2006	Yuki Takii	TIP-06-1314	2791

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EXAMINER

KILPATRICK, BRYAN T

ART UNIT	PAPER NUMBER
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1772

NOTIFICATION DATE	DELIVERY MODE
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12/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Office Action Summary	Application No. 10/593,680	Applicant(s) TAKII ET AL.	
	Examiner BRYAN T. KILPATRICK	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The arguments/remarks filed on 12 October 2010 have been entered and fully considered.
2. The request for continued examination under 37 CFR 1.114 filed on 11 May 2010 has been entered and fully considered.
3. Instant claims 1-14 are pending currently.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,770,461 (Sakazume et al.), and further in view of U.S. Patent No. 4,815,978 (Mazza et al.).

In regards to instant claim 1, Sakazume et al. discloses a method and apparatus for separating magnetic particles that have immunocomplexes bound upon them, then flocks of the bound magnetic particles are made using a magnetic field, which are then bound to the reaction container walls that the materials are located inside via a stronger magnetic field (Abstract). Furthermore, Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34).

Sakazume et al. discloses the use of a nozzle for removing unnecessary liquids in the Abstract, but it does not expressly disclose the use of a mixing medium such as air. However, Mazza et al. recites in claims 1-31 and Figure 9 an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle. In addition, Mazza et al. discloses the use of a cuvette sealer (16 of Fig. 1-2) that seals the tops of used cuvettes that contain samples, reagents, and mixing contents (col. 7, lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nozzle of Sakazume et al. to supply an air jet for mixing, similarly to the method and apparatus taught by Mazza et al. The motivation would have been to be capable of thoroughly mixing the contents in a reaction container (Mazza et al. Abstract) in addition to being capable of removing liquid material when needed (Sakazume et al. Abstract).

In regards to instant claims 2-3, Sakazume et al. discloses magnetic particles for immobilization that can bind to the walls of a reaction container (Abstract). Magnetic particles in a solution can be bound to the bottom of an analysis container using a magnetic field (Abstract of Sakazume et al.), and while using an air jet that has a jet pressure that is not strong enough to remove all of the contents in the container by splashing, the solution can be agitated and/or mixed using an air jet that does not interact with the magnetic particles, which would be bound to the bottom of the container (similar to the invention disclosed in the Abstract of Mazza et al.).

In regards to instant claim 4, claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles.

In regards to instant claims 5 and 7, claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles. Sakazume et al. discloses a method and apparatus for separating magnetic particles that have immunocomplexes bound upon them, and then flocks of the bound magnetic particles are made using a magnetic field, which are then bound to the reaction container walls that the materials are located inside via a stronger magnetic field (Abstract). Mazza et al. recites in claims 1-31 and Figure 9 of an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle. In addition, Mazza et al. discloses the use of a cuvette sealer (16 of Fig. 1-2) that seals the tops of used cuvettes that contain samples, reagents, and mixing contents (col. 7, lines 13-16).

In regards to instant claims 6, 8, and 11; Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34) for mixing.

In regards to instant claim 9, Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and further employs an agitation device (col. 5, lines 16-34) for agitating a reaction container. Claim 4 of Sakazume et al. recites diameters

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for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles.

In regards to instant claims 10 and 12, claim 4 of Sakazume et al. recites diameters for magnetic particles used to be 1-2 micrometers or 10-50 micrometers.

In regards to instant 13, Sakazume et al. discloses the analysis of a biological sample in col. 3, line 64. It is well known in the art that nucleic acids are encompassed by biological samples.

In regards to instant claim 14, Sakazume et al. discloses the binding and analysis of samples in a solution (col. 3, line 63 – col. 4, line 11).

Response to Arguments

Applicant's arguments/remarks filed 12 October 2010 have been fully considered but they are not persuasive.

Applicant states on p. 1 and 3-4 of the remarks that Sakazume et al. does not teach or disclose a number of convexes with top faces and that the "containers" of the prior art are conventional cylindrically-shaped vessels, with regards to instant claim 5. As previously stated above, claim 4 of Sakazume et al. recites diameters for magnetic particles used for immobilizing immunocomplexes, which suggest circular particles - it is well known for circular objects to have concave or convex surfaces. Regarding this remark, it is unclear whether Applicant is discussing the carrier that a substance is

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bound too (recited in instant claims 1 and 5) or the container that holds the binding carrier in solution (recited instant claim 7).

Applicant states on p. 2-3 of the remarks that the combination of Sakazume et al. and Mazza et al. does not meet the limitations of a sealing step and an air-mixing medium, concerning instant claims 1 and 5. As previously stated above, Sakazume et al. discloses a method and apparatus for separating magnetic particles that have immunocomplexes bound upon them, and then flocks of the bound magnetic particles are made using a magnetic field, which are then bound to the reaction container walls that the materials are located inside via a stronger magnetic field (Abstract). Sakazume et al. discloses a method where applying varying magnetic fields causes rotational motion (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) of magnetic particles, and employing an agitation device (col. 5, lines 16-34). Sakazume et al. discloses the use of a nozzle for removing unnecessary liquids in the Abstract, but it does not expressly disclose the use of a mixing medium such as air. However, Mazza et al. recites in claims 1-31 and Figure 9 an apparatus and method for mixing liquid samples in a cuvette using an air jet supplied through a nozzle. In addition, Mazza et al. discloses the use of a cuvette sealer (16 of Fig. 1-2) that seals the tops of used cuvettes that contain samples, reagents, and mixing contents (col. 7, lines 13-16). Since Sakazume et al. discloses employing an agitation device (col. 5, lines 16-34) and a method of applying magnetic fields for moving (col. 3, lines 1-2) and shaking (col. 3, lines 16-20) magnetic particles, the combination of Sakazume et al. and Mazza et al. appears more than capable of adding air bubbles to a cuvette (Mazza et al.) before sealing the cuvette

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(Sakazume et al.), and then agitating the cuvette with samples in a solution are magnetically bound to the bottom of the cuvette (Sakazume et al.). Regarding the air jets of Mazza et al., the prior art discloses the use of a valve 152 that is controlled by controller 155 for controlling an air supply 153 through an air line 154 to a nozzle 150 (Fig. 4); therefore, an operator is more than capable of controlling the amount and pressure of air discharged into a cuvette – the most probable motivation for using a low pressure would be to prevent the splashing out all the contents contained within a cuvette.

Applicant states on p. 4 of the remarks, with respect to instant claims 1 and 5, that the sealing step of Sakazume et al. takes place at the end of a process. Mazza et al. discloses the use of a cuvette sealer (16 of Fig. 1-2) that seals the tops of used cuvettes that contain samples, reagents, and mixing contents (col. 7, lines 13-16). It has been held by the Courts that the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results - *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); MPEP 2144.04 Legal Precedent..., IV. CHANGES IN SIZE, SHAPE, OR SEQUENCE..., C. Changes in Sequence.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571)272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. T. K./
Examiner, Art Unit 1772

/SAM P SIEFKE/
Primary Examiner, Art Unit 1772